



Ideen bewegen mehr

AAT Alber Antriebstechnik GmbH · PF 100560 · D-72426 Albstadt

Kinco Corporation ApS
Overgårdvej 4
DK-7500 Holstebro

Albstadt, den 22. Juni 2022

IMPORTANT: V-MAX² Pushing and Braking Aid Recovery

Dear Sir or Madam,

in the course of our permanent market observation and quality control we have found out:

In some cases, a threaded pin in the guide sleeve of individual V-MAX² pushing and braking aids was not glued properly from February 2022 to June 2022. Under unfavorable conditions, these devices may freewheel without braking effect.

As a trained medical supply store, you have the option of carrying out the corrective measure directly at your customer's site in accordance with the instructions. You can plan a time of approx. 10 minutes for the corrective measure. For your efforts, we will reimburse you 130 EUR per device.

Until the corrective action has been carried out by you on site, these V-MAX² must not be used any more for safety reasons.

If you have any questions, please contact our service team directly by mail servicecenter@aat-online.de or phone + 49 7431 12 95 550.

Thank you in advance. We apologize for any inconvenience this may cause.

It is ensured that all V-MAX² produced in the future will be delivered exclusively with flawless guide sleeves.

With kind regards

A handwritten signature in blue ink, reading 'Griepenkerl', written in a cursive style.

Dr. Kordt Griepenkerl
Managing Director AAT Alber Antriebstechnik GmbH

Unsere Hausanschrift
AAT Alber Antriebstechnik GmbH · Ehestetter Weg 11 · D-72458 Albstadt-Ebingen
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Unsere Bankverbindungen
Skandinaviska Enskilda Banken
Swift Code: ESSESESS
DE70 5122 0200 0071 4760 06

Amtsgericht Albstadt HRB 401006 · Sitz: Albstadt · Ust ID Nr. DE 173669635
Geschäftsführer: Dr. Kordt Griepenkerl



Kinco Corporation ApS
Overgårdvej 4
DK-7500 Holstebro

Urgent safety information

*Recall
affecting
V-MAX² P1605*

Albstadt, 22 June 2022

Sender:

AAT Alber Antriebstechnik GmbH, Ehestetter Weg 11, D 72458 Albstadt – Ebingen, Germany

Addressee:

See address header above

Identification of the affected medical products:

Trade name:	V-MAX ²
Name of Model and/or number:	P1605
Serial number:	See supplementary sheet

Description of the problems including the detected cause:

The grub screw in the guide sleeve of some V-MAX² pushing and braking aids was not properly installed as of February 2022 to June 2022.

As a result, the connection of the two-part guide sleeve came loose.

Potential risk:

- Sudden loss of the propulsion and braking effect

In this case, the product is no longer functional. It cannot be ruled out that this could result in a safety risk for the user of the braking and pushing aid. If the loss of the drive occurs, for example, on a steep incline, adverse conditions could result in the operator being unable to maneuver the wheelchair without the braking function of the pushing and braking aid.

The situation described with regard to the affected component occurred exclusively in a delimited delivery batch.



Which measures should the addressees take?

- Use the concerned V-MAX² not any longer
- As a trained medical supply store, you have the option of carrying out the corrective measure directly on your customer's premises in accordance with the instructions. Notify us of the implementation of the corrective measure using the enclosed registration form.

Distribution of the here described safety information

Please make sure that all users of the above mentioned products and other persons involved are informed about these **Urgent Safety Informations**. Should you have given the product to a third party, please send a copy of this information along or inform the contact person stated below.

Please keep these informations at least until measures have been completed.

The Federal Institute for Drugs and Medical Devices received a copy of these „Urgent Safety Informations“.

Contactperson:	<i>for collecting, reshipment, repair and/or exchange of affected medical devices</i>	<i>Persons responsible for regulatory compliance (according to Art. 15, EU Medical Device Regulation 2017/745):</i>	
	<i>Service - Center</i>	<i>Daniel Mohr PRRC</i>	<i>Kordt Griepenkerl Debuty PRRC</i>
Tel.:	<i>+ 49 7431 12 95 550</i>	<i>+ 49 7431 12 95 502</i>	<i>+ 49 7431 12 95 0</i>
Fax:	<i>+ 49 7431 12 95 540</i>	<i>+49 74 31 12 95 37</i>	<i>+49.74 31.12 95 35</i>
e-mail:	servicecenter@aat-online.de	sicherheitsbeauftragter-mp@aat-online.de	

We regret any inconvenience this may cause you and thank you in advance for your cooperation.

Best regards,

AAT Alber Antriebstechnik GmbH
Daniel Mohr

Person responsible for regulatory compliance acc. to Art. 15, EU Medical Device Regulation 2017/745



Ideen bewegen mehr

The exact procedure of the return for the specialized trade is as follows:

1. upon receipt of the mailing.
 - > Please contact the customer concerned
 - > As a trained medical supply store, you have the possibility, according to the instructions, to carry out the corrective measure directly at your customer's site. You can plan a time of approx. 10 minutes for the corrective action.
2. please contact AAT Alber Antriebstechnik
 - > If you have carried out the corrective action yourself, please notify us that the corrective action has been carried out.
You are welcome to use the attached form for this purpose
3. after receiving the goods
 - > We will send you the compensation for expenses immediately after the feedback of the execution of the correction measure.

- If you have any questions, please contact us directly by mail servicecenter@aat-online.de or phone +49 7431 12 95 550 to our service team.

- Thank you in advance. We apologize for any inconvenience caused.

- It is ensured that all v-max² produced in the future will be delivered exclusively with flawless guide sleeves.

Unsere Hausanschrift
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Geschäftsführer: Dr. Kordt Griepenkerl

The following serial numbers are affected:

Serial number	Commission	Order number	Date
P1605220110	v-max ² DEMO	v-max ² DEMO	2/15/2022
P1605220543	v-max ² B + max-e	v-max ² B + max-e	5/24/2022
P1605220542	v-max ² B + max-e	v-max ² B + max-e	5/24/2022
P1605220544	v-max ² B + max-e	v-max ² B + max-e	5/24/2022
P1605220389	v-max ² B + max-e	v-max ² B + max-e	4/8/2022
P1605220395	v-max ² B + max-e	v-max ² B + max-e	4/8/2022
P1605220388	v-max ² B	v-max ² B	4/8/2022
P1605220390	v-max ² B	v-max ² B	4/8/2022



Registration form product return V-MAX²

Affected product:

V-MAX²

Your details:

Medical supply store:

Kinco Corporation ApS
22202034
DK - 7500 Holstebro

Customer number:

302880

System-/Seriennummer:

Please send this form filled out to the following fax number or e-mail address:
Fax no. : +49-5425-9402-20 / servicecenter@aat-online.de

The corrective action was performed according to the instructions

Datum:

Name / Unterschrift: